



JPW

PATENT
Customer No. 22,428
Atty. Dkt. No. 080618-0237

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John P. Cooke et al.

Title: ENHANCEMENT OF VASCULAR FUNCTION BY MODULATION
OF ENDOGENOUS NITRIC OXIDE PRODUCTION OR ACTIVITY

Appl. No.: 10/618,835

Filing Date: 07/15/2003

Examiner: J. Russel

Art Unit: 1654

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR § 1.97(b)

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under 37 CFR §§ 1.56 and 1.97(b), Applicants bring to the Examiner's attention the documents on the attached SB/08. This Information Disclosure Statement is being filed before the mailing date of a first Office action on the merits for the above-referenced application.

This application is a continuation of U.S. Application No. 10/060,252, filed February 1, 2002, now U.S. Pat. No. 6,646,006, which application is a continuation of U.S. Application 09/930,833, filed August 15, 2001, now abandoned, which application is a continuation of U.S. Application No. 09/075,509, filed May 8, 1998, now U.S. Pat. No. 6,337,321, which application is a continuation of 08/556,035, filed November 9, 1995, now U.S. Pat. No. 5,891,459, which application is a continuation-in-part of U.S. Application No.

08/336,159, filed November 8, 1994, now abandoned, which application is a continuation-in-part of 08/076,312, filed June 11, 1993, now U.S. Pat. No. 5,428,070.

A. Submitted Search Reports

Four search reports are submitted herewith.

PCT/US94/06203 (G42): This application is an international application that claims the benefit of the '312 application. The search report lists documents considered to be relevant by the searcher. All of the listed documents are believed of record.

PCT/US96/17241 (G43): This application is an international application that claims the benefit of the '035 application. The search report lists documents considered to be relevant by the searcher. Documents G1 and G3 are submitted herewith. The remaining documents are believed of record.

PCT/US97/13905 (G44): This application is an international application that claims the benefit of U.S. application 08/695,792, a continuation of the '035 application. The search report lists documents considered to be relevant by the searcher. Documents G8, G12, G13 and G16 are submitted herewith. The remaining documents are believed of record.

EP 97 93 8163 (G41): This application is an European application resulting from PCT/US97/13905. The search report lists documents considered to be relevant by the searcher, in addition to the references listed in the search report of international application PCT/US97/13905 . Documents G19 – G22 are submitted herewith. The remaining documents are believed of record.

B. Documents Submitted to or cited by the Office in an earlier filed case

Documents G23 – G37 and G39 – G40 were cited by or submitted to the Office in at least one of Application No. 08/076,312, filed June 11, 1993; Application No. 08/336,159, filed November 8, 1994, and Application No. 08/556,035, filed November 9, 1995. As provided in 37 CFR §1.98(d), a copy of these documents are not being submitted since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent applications, upon which the present application claims priority benefit.

Documents G1 – G18 and G38 were cited by or submitted to the Office in related Application No. 08/796,298, filed February 7, 1997, or Application 08/764,919, filed December 16, 1996. Copies of these documents are submitted herewith.

Documents G24 and G25 are cited on Form PTO/SB/08 with ellipses in the title of the journal articles. Applicants note that the articles were cited by the Examiner in Application No. 08/556,035, filed November 9, 1995, in this manner.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute “prior art” under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

The Commissioner is hereby authorized to charge any fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 07-16-2004

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5569

Facsimile: (202) 672-5399

By Sean A. Passino (45,943) For
SEAN A. PASSINO
Stephen B. Maebius
Attorney for Applicant
Registration No. 35,264

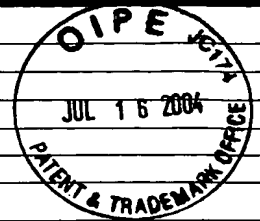
Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/618,835
Filing Date	7/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

[illegible][illegible]Date
Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: July 16, 2004 (use as many sheets as necessary)				Complete if Known	
				Application Number	10/618,835
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				First Named Inventor	John P. Cooke
				Group Art Unit	1654
				Examiner Name	J. Russel
				Attorney Docket Number	080618-0237
Sheet	2	of	3		

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	G23	LEFER ET AL., "Role of Endothelium-derived Relaxing Factor as a Cardioprotective Agent in Myocardial Ischemia", <i>Basil, Karger</i> (1990), pp. 190-197.	
	G24	IGNARRO ET AL., "Basic Polyamino Acids Rich in Arginine . . .", <i>Circ. Res.</i> (Feb. 1989), Vol. 64, No. 2, pp. 315-329.	
	G25	ROCK ET AL., "L-arginyl-L-lysine and L-arginyl-L-arginine . . .", <i>Med. Sci. Res.</i> (1990), Vol. 18, pp. 165-166.	
	G26	CAYATTE, Antonio J., et al., "Chronic Inhibition of Nitric Oxide Production Accelerates Neointima Formation and Impairs Endothelial Function in Hypercholesterolemic Rabbits," <i>Arteriosclerosis and Thrombosis</i> , Vol. 14, No. 5, 753-759 (May 1994).	
	G27	DREXLER, Helmut, et al., "Effect of L-Arginine on Coronary Endothelial Function in Cardiac Transplant Recipients," <i>Circulation</i> , Vol. 89, No. 4, 1615-1623 (Apr. 1994).	
	G28	FITZPATRICK, David F., et al., "Endothelium-Dependent Vasorelaxing Activity of Wine and Other Grape Products," <i>American Journal of Physiology</i> , Vol. 265, No. 2, H774-778 (Aug. 1993).	
	G29	NARUSE, Kenshin, et al., "Long-Term Inhibition of NO Synthesis Promotes Atherosclerosis in the Hypercholesterolemic Rabbit Thoracic Aorta," <i>Arteriosclerosis and Thrombosis</i> , Vol. 14, No. 5, 746-752 (May 1994).	
	G30	TSAO, Philip S., et al., "L-Arginine Attenuates Platelet Reactivity in Hypercholesterolemic Rabbits," <i>Arteriosclerosis and Thrombosis</i> , Vol. 14, No. 10, 1529-1533 (Oct. 1994).	
	G31	VERMA, et al., <i>Nature</i> , Vol. 389, pp. 239-242 (1997).	
	G32	SHEARS, et al., <i>J. Am. Coll. Surg.</i> , Vol. 187, pp. 295-306 (1998).	
	G33	SAWA, et al., <i>Circulation</i> , Vol. 96 (Suppl. II) 280-285 (1997).	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet	3	of	3
		Attorney Docket Number	080618-0237

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	G34	BAI, et al. <i>Ann. Thorac. Surg.</i> , Vol. 66, pp. 814-820 (1998).	
	G35	LUI, et al., <i>Current Pharmaceutical Design</i> , Vol. 2, pp. 553-584 (1996).	
	G36	MARSHALL, et al., <i>Science</i> , Vol. 269, pp. 1050-1055 (Aug. 1995).	
	G37	ORKIN, et al. "Report and Recommendations of the Panel to Assess the NIH Investment on Research in Gene Therapy", (1995).	
	G38	ROČIĆ ET AL., "L-arginyl-L-lysine and L-arginyl-L-arginine", <i>Med. Sci. Res.</i> (1990), Vol. 18, pp. 165-166.	
	G39	ADAMS ET AL., "Oral L-Arginine Inhibits Platelet Aggregation but Does Not Enhance Endothelium-Dependent Dilation in Healthy Young Men", <i>JACC</i> (October 1995), Vol. 26, No. 4, pp. 1054-1061.	
	G40	MAYER ET AL., "Homocysteine and Coronary Atherosclerosis," <i>JACC</i> (March 1, 1996), Vol. 27, No. 3, pp. 517-527.	
	G41	Supplementary European Search Report dated May 12, 2004 for EP Application No. 97938163.9	
	G42	International Search Report dated August 29, 1994 for PCT Application No. PCT/US94/06203.	
	G43	International Search Report dated January 21, 1997 for PCT Application No. PCT/US96/17241.	
	G44	International Search Report dated October 10, 1997 for PCT Application No. PCT/US97/13905.	

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